

Regulatory Consensus on Health Care Issues

Waste/Hazardous Waste/Pharmaceutical Waste • April 2008

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Background

Health care facilities are those like hospitals, doctor offices, laboratory clinics, etc. These facilities must address issues related to and manage many kinds of wastes unique to the health care industry. For example: laboratory wastes, pharmaceutical wastes, and wastes from cleaning and sterilizing procedures. These wastes can be hazardous because they display a hazardous characteristic or because they are specifically listed on the regulations in the F, P or U list codes (see *Guide to Terms and Abbreviations* below).

Purpose

This document suggests ideas and steps health care providers can take to properly manage wastes generated in your hospital. Hospitals have the potential to generate large amounts of hazardous wastes. If not managed properly, hazardous waste can pose threats to public safety and to the environment. Proper management of chemicals and wastes can help reduce your regulatory liability. Your hospital is most likely already doing some, but not all, of the best management practices suggested in this document. This document offers regulatory consensus on issues at health care facilities, and how the Division of Waste Management, through the Hazardous Waste Branch, has interpreted each issue.

Guide to Terms and Abbreviations

The following terms and abbreviations are used throughout this document:

Bulk Chemo Waste: Waste materials that have been saturated with chemotherapy agents. Examples: spill clean-up materials, non-empty vials, unused IVs, and chemotherapy agents having waste codes beginning with P, U or D.

Characteristic: Refers to hazardous characteristics that a waste may exhibit (see, 401 KAR 31:030 at http://www.waste.ky.gov/NR/ronlyres/31882E93-BB70-457D-81AA-48F7E8CDBD92/0/401_KAR_31_030.doc)

Empty: A container that held hazardous materials must meet certain criteria to be deemed *empty*.

Listed: Refers to a chemical being named on the F, P or U list because it exhibits a hazardous characteristic (401 KAR 31:040).
http://www.waste.ky.gov/NR/ronlyres/1B8832E0-6829-4D5B-8C25-511AF182A105/0/401_KAR_31_040.doc

KDWM: Kentucky Division of Waste Management

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HWB: Hazardous Waste Branch

POTW: Publicly Owned Treatment Works – your local sewer authority (e.g. wastewater treatment plant)

Trace Chemo Waste: waste materials that have come into contact with or may contain a few drops of a chemotherapy agent. Examples: empty vials, syringes, IVs, tubing, gowns, gloves, etc. Materials contaminated with more than a very small amount are classified as *Bulk Chemo Waste*.

Waste/Issue	Regulatory Agency Consensus
Barium Sulfate Contrast Media	Each individual facility must evaluate and document its waste barium sulfate oral contrast media before disposal to determine whether it is characteristically hazardous for barium (it contains barium at a concentration of 100.0 parts per million or more).
Chlorofluorocarbon (CFC) Inhalers	<p><i>Empty</i> inhalers (those containing no product and no pressure) are exempt from hazardous waste rules. Recycle, if possible, or manage as an industrial solid waste according to solid waste rules.</p> <p><i>Non-empty</i> inhalers must be evaluated to determine whether they are hazardous, then managed accordingly; or, they may be managed as a hazardous waste without evaluation.</p>
Chemotherapy Waste	<p>Dispose of all containers (including vials, tubing, etc.) that still hold liquid chemo waste in the <i>bulk</i> hazardous chemotherapy waste stream.</p> <p>Empty containers may be disposed of as <i>trace</i> chemo waste. See the <i>Empty Containers</i> section below.</p> <p>Note: Safe work practices dictate that materials (such as syringes, vials, etc.) contaminated with chemotherapeutic agents <i>not</i> be handled after use to minimize exposure to the health care worker. Therefore, Kentucky hazardous waste staff strongly recommend that health care workers dispose of all chemotherapy waste containers holding free liquid in the <i>bulk</i> chemotherapy hazardous waste stream rather than attempting to empty them.</p>
Cidex OPA™	Many health care providers are switching from glutaraldehyde to Cidex OPA™ – a cold sterilant containing 0.55% ortho-phthalaldehyde. Information provided by Johnson and Johnson (the manufacturer) states that solutions having a concentration of less than 27% Cidex OPA™ are not considered to be hazardous. Provided it contains no other hazardous constituents, a solution of less than 27% Cidex OPA™ is deemed nonhazardous. Cidex OPA is an aquatic toxicant; prudent practice suggests neutralizing the OPA with glycine before discharge to the POTW or sanitary sewer.
Contractor Policy Includes Healthcare Providers	By formal policy, the Kentucky Division of Waste Management allows certain contractors to transport used materials (potential wastes) to their place of business for evaluation, collection and proper disposal. Home health care providers, including those using personal vehicles for business purposes, are included in this policy. This means they can transport used materials to the health care facility for proper evaluation and management.
Controlled Substances	Controlled substances destined for disposal as a waste are presumed to be hazardous unless proven otherwise by the waste generator. When these substances are discharged to a sanitary sewer system in accordance with Drug Enforcement Administration (DEA) regulations, you must report the kinds and amounts to your hazardous waste regulatory authority <i>and</i> your local sewer authority (POTW).

Waste/Issue	Regulatory Agency Consensus
Empty Containers	<p>Unless it held a chemical named on the <i>P list</i>, a container is only considered empty when:</p> <ul style="list-style-type: none"> • All waste that can be removed has been removed using the practice commonly employed, and • No more than 1 inch residue remains in the bottom of the vial, or • No more than 3% by weight of the total capacity of the container (vial) remains in the container. <p>To determine whether a chemical is on the <i>P list</i> and to find out about the triple-rinsing criteria necessary before its container can be considered <i>empty</i>, see 401 KAR 31:040.</p>
Epinephrine Vials and Syringes	<p>Vials that contained epinephrine and other materials in contact with this P-listed waste, must be disposed of as an acutely hazardous (P-listed) waste.</p> <p>EPA states: “Epinephrine residue in a syringe is not P042” (see http://yosemite.epa.gov/osw/rcra.nsf/0c994248c239947e85256d090071175f/1c1deb3648a62a868525670f006bccd2?OpenDocument).</p> <p>Therefore, a syringe that has delivered a full dose of epinephrine (was used for its intended purpose) and contains only residual “epi” can be disposed of in the <i>infectious waste sharps</i> waste stream.</p> <p>Note: See Epinephrine Q3 for additional updated information.</p>
Formaldehyde & Formalin (<i>solutions of formaldehyde, methanol and water</i>)	<p>Solutions having a concentration of 20% or more formaldehyde are considered hazardous waste and cannot be discharged to a sanitary sewer system.</p> <p>Used solutions having a concentration of less than 20% formaldehyde are not considered hazardous waste, but can only be discharged to a sanitary sewer system if the operator grants permission to do so. You must report to your local sewer authority any amount of formalin at any concentration discharged into the sanitary sewer system. Your hazardous waste regulatory staff may also require that you report the amounts and concentrations discharged.</p> <p>Under no circumstances should waste formalin or formaldehyde solutions be discharged to a septic system!</p> <p><i>Unused</i> solutions in which formaldehyde is the sole active ingredient are U-listed hazardous waste (U122) at all concentrations and must be managed as hazardous waste.</p>

Waste/Issue	Regulatory Agency Consensus
Glutaraldehyde	<p>Glutaraldehyde is typically used in a 2.0-2.5% solution. It loses its effectiveness at 1.5%. If, after use, the concentration of a solution is 1.5% or less glutaraldehyde, some POTWs may allow it to be discharged to the sanitary sewer system; however, discharging more concentrated solutions may be prohibited.</p> <p>Remember to notify your local sewer authority before discharging this or any other chemical waste.</p>
Inspection of Pipe to Sanitary Sewer	<p>Large and small quantity hazardous waste generators, including health care facilities, are required to comply with 401 KAR 34:030 Section 2, <i>Preparedness and Prevention – Design and Operation of a Facility</i>. This requires that facilities be maintained and operated to minimize the possibility of a fire, explosion or any unplanned sudden or non-sudden release to air, land, or water of hazardous waste or hazardous waste constituents that could threaten human health or the environment. KDWM regulatory authorities interpret this rule to include the pipes leading from the facility to the sanitary sewer when they are used to conduct hazardous waste.</p> <p>For this reason, KDWM hazardous waste staff strongly recommends that health care facilities inspect pipes to ensure that no piping and appurtenances owned or utilized by the generator and leading to the public sewers, will release any hazardous waste or hazardous waste constituents to the environment.</p>
Intravenous (IV) Bags and Sealed Tubing	<p>An IV bag and its attached tubing are considered a <i>container</i> – not a dispensing instrument. Unless it held a P-listed material, the bag and tubing are considered empty when all free liquids have been removed by normal practical means <i>and</i> any residual liquid remaining is less than 3% of the total volume. If an IV bag and tubing do not meet <i>empty</i> criteria, the remaining liquid must be evaluated to determine whether it is hazardous and the waste managed appropriately.</p>

Waste/Issue	Regulatory Agency Consensus
Pharmaceutical Waste	<p>Health care providers must evaluate all pharmaceutical waste before disposal to determine whether it is hazardous waste.</p> <p>For more information, see KDEP fact sheet, <i>Evaluating Pharmaceutical Wastes</i>, available at www.waste.ky.gov and at www.dca.ky.gov</p>

Waste/Issue	Regulatory Agency Consensus
Reverse Distribution of Pharmaceutical Drugs	<p>The health care provider must decide whether an unused and unneeded pharmaceutical is potentially usable. If unusable, the pharmaceutical is a waste; evaluate it (at the site of generation) to determine whether it is hazardous. Those pharmaceuticals determined to be (1) a waste and (2) hazardous must be managed as hazardous at the generation site and disposed of as a hazardous waste. All other pharmaceuticals may be sent to a reverse distributor for potential reuse. Examples of pharmaceuticals that typically cannot be returned for credit are repackaged unit doses and manufacturer's samples.</p> <p>Keep records on site of your facility's contract with its reverse distributor. This contract will document the point at which materials at your facility may be considered products or must be considered wastes.</p> <p>Only products can be returned to a reverse distributor (not waste). If you are returning products, it is not necessary to evaluate them to determine whether they would be hazardous when wasted. Your pharmaceuticals are products acceptable for return if they meet the following criteria:</p> <ol style="list-style-type: none"> 1. They must have been under the control of the health care facility at all times (this excludes all pharmaceuticals that have been in the hands of the patient); 2. They must be in a container that is in good condition (this excludes items like tubes that are oozing product); and 3. They must not have been repackaged in unit doses (this excludes manufacturer's samples and unused patient medications) <p>A reverse distributor will also accept partially-used containers of pharmaceuticals that meet criteria #1 above, and pharmaceuticals past their expiration date.</p> <p>Keep records on site of your facility's contract with its reverse distributor and receipts from each shipment. Should receipts show that a reverse distributor always disposes of a certain pharmaceutical as a waste, you should ask whether it is because that pharmaceutical can never be reused. If it can never be reused (i.e. it is always a waste), you will need to declare and managed it as a waste at your site – not send it for reverse distribution.</p> <p>Note: Since manufacturer's samples are never acceptable for reverse distribution, KDWM and DCA hazardous waste staffs strongly recommend that you only accept those you are able to use before the expiration date or ask for samples with a longer expiration date to avoid having to dispose of unused samples as hazardous waste.</p>

Waste/Issue	Regulatory Agency Consensus
Stains	<p>Evaluate, <i>at the point of generation and before mixing</i>, each waste produced during the staining process to determine whether it is hazardous.</p> <p>Collect, manage and dispose of as hazardous all staining-process waste that has not been evaluated or that has been evaluated and determined to be hazardous.</p> <p>Notify the local sewer authority of all staining waste discharged to the sanitary sewer. Report all <i>hazardous</i> staining waste to your hazardous waste regulatory authority, including wastes having a concentration of greater than 24% alcohol which may be ignitable hazardous waste.</p>
Wastes Discharged to a Sanitary Sewer System	<p>Evaluate, <i>at the point of generation and before mixing</i>, each waste discharged to a sanitary sewer system to determine whether it is hazardous and for local discharge requirements. Notify your local sewer authority of each waste that is being discharged; report to your hazardous waste regulatory authority all <i>hazardous</i> wastes that are being discharged.</p> <p>Exception: A patient's body is not considered to be a <i>point of generation</i>. Hazardous chemicals removed from a patient's body are not considered <i>generated</i>. For example chemotherapy agents injected during bladder insillations, which are then eliminated, are interpreted as being <i>used as they are intended</i> and not <i>generated</i>. Current best management practices recommend sending chemicals eliminated from a patient's body to a POTW or sanitary sewer.</p>

Waste/Issue	Regulatory Agency Consensus
Laboratory Wastes	<p>Ictotest Tablets: Unreacted tablets are presumed to be hazardous for the characteristic of reactivity (D003). Since used ictotest tablets are a solid material, they are not suspected of being hazardous for the characteristic of corrosivity. However, dissolving the tablets in water creates a corrosive liquid (D002) hazardous waste that must be neutralized onsite or sent offsite as a hazardous waste. If neutralized onsite, please check with KDWM for possible onsite treatment permit applicability. The neutralized waste may be discharged to a POTW after proper notification.</p> <p>Clinitest Tablets: Unreacted tablets are presumed to be hazardous for the characteristic of reactivity (D003). Reacted tablets must be disposed of as a hazardous waste unless you have a documented evaluation showing it is nonhazardous.</p> <p>Clinistix Strips: Evaluate onsite.</p> <p>Blood Analyzer Wastes: Blood analyzer units generate a waste consisting of blood mixed with chemical reagents. The analyzer waste is typically contained in a cuvette or bubble pack, or discharged directly to the sanitary sewer. Evaluate the analyzer waste for the hazardous characteristics. Waste evaluations may consist of (1) information from the manufacturer certifying the reagents do not contain chemicals meeting EPA and KDWM characteristic waste criteria, or (2) test results from a representative sample of waste analyzed by an independent laboratory. Work with the independent laboratory and your inspector to determine the best method of obtaining a representative sample.</p> <p>Hemacue Cuvettes: These are considered to be infectious waste. Dispose of waste hemacue cuvettes as such.</p>

Related questions

Q1. Are the wrappers or vials from P-listed drugs (like warfarin or nicotine patches) considered hazardous P-listed waste?

A1. Yes. State and federal regulations state the following are P-listed hazardous wastes:

- Non-hazardous waste mixed with P-listed hazardous waste;
- Spill clean-up debris from P-listed materials; and
- Wrappers and vials that held P-listed drugs.

Q2. How does one list waste codes on a manifest for pharmaceuticals shipped in lab packs?

A2. Waste codes: You must use the new federally mandated manifest and its continuation sheet to list all applicable waste codes.

Q3. Is epinephrine (epi) waste resulting from the operating room practices listed below considered a P-listed hazardous waste?

A3. In a recent EPA Memo (October 15, 2007), the EPA concluded that epinephrine salts commonly used in hospital settings are not within the scope of the P042 listing. This memo can be found at <http://yosemite.epa.gov/osw/rcra.nsf/b36c11f3e4ba870485256d0900711760/2f701627eb73b2ab852573d2005e0b4f!OpenDocument>

Q4. Are HEPA filters from the chemotherapy-preparation hood a hazardous waste?

A4. HEPA filters in chemo prep hoods may fail the limits for arsenic or cresol if drugs with those hazardous waste characteristics are prepped in that area. Evaluate the filters for hazardous waste characteristics to determine whether they are hazardous. For more information on hazardous waste characteristics, see http://www.waste.ky.gov/NR/rdonlyres/31882E93-BB70-457D-81AA-48F7E8CDBD92/0/401_KAR_31_030.doc.

Q5. Are alcohol hand sanitizers and gels ignitable (D001)?

A5. Alcohol hand sanitizers, when used as they were intended, do not generate a hazardous waste. Unused hand sanitizers and gels are suspected to be hazardous for the characteristic of ignitability (D001).

Q6. Are dusts and particles from P-listed drugs on a preparation surface considered to be a P-listed hazardous waste?

A6. Yes. However, visual inspection of surfaces and materials that come in contact with P-listed drugs should be adequate to identify whether contamination has occurred and whether the soufflé cup or wipe used to clean the surface should be managed as a hazardous P-listed waste.

Q7. Must I manage waste from ambulances that service our facility?

A7. Kentucky statutes require hospitals to accept properly labeled and packaged infectious waste only from ambulances servicing their facility. Hospitals may choose whether or not to accept unknown waste or hazardous waste from other ambulances. Unknown or hazardous waste accepted from other ambulances must be managed identically to the hospital's own waste.

Q8. Is the product Glut-out™ a hazardous waste after use?

A8. The manufacturer of Glut-out™ has determined that when directions for use have been followed, waste Glut-out™ is not a hazardous waste.

Q9. How should I label containers of unsorted waste pharmaceuticals containing both non-hazardous and hazardous waste?

A9. Satellite accumulation containers of unsorted waste pharmaceuticals must be managed as hazardous waste containers. Be sure to segregate P-listed hazardous waste from the rest of the contents of the container to avoid accumulating more than one quart of P-listed waste at one satellite location. (If P-listed waste is mixed in, all the waste is considered *P-listed* and involves more stringent requirements.) There are two ways to segregate: (1) the facility can use a separate container for P-listed waste or (2) the facility can place each P-listed waste in a sealed plastic bag before placing it in the satellite accumulation container.

Q10. How can I effectively evaluate patient skin/surgical preparation materials?

A10. Many patient skin/surgical preparatory materials/solutions contain alcohol in excess of 24% making the waste material an ignitable hazardous waste (D001). Waste patient prep materials must be *dry* and *empty* as defined by RCRA.

Dry means that no fluid from the material drips when the wipe is mechanically wrung. For example: If you wring a 2x1 inch alcohol wipe after you use it and it does not drip excess material when wrung, that used wipe would be considered *dry* and would not be an ignitable hazardous waste.

Empty means the container must be evacuated by all reasonable means *and* cannot contain liquid in excess of 3% volume of the container. For example, in the case of Duraprep™ swabs, which consist of a container attached to a sponge, the sponge must be evaluated to determine whether it is dry upon disposal. If, after use, liquid remains in the container (as is often the case), it would *not* be considered *empty*, and must therefore be managed as an ignitable (D001) hazardous waste.

More Information

The DCA and KDWM hazardous waste offices also have staff that can help you. Contact DCA, HWB or the KDWM regional office nearest your facility at the numbers below.

KDWM staff can provide information and resources to help you reduce waste.

Field Operations Hazardous Waste Offices

Central Office (502-564-6716)
Bowling Green (270-746-7475)
Columbia (270-384-4735)
Florence (859-525-4923)
Frankfort (502-564-3358)
Hazard (606-435-6022)
London (606-330-2080)
Louisville (502-429-7120)
Madisonville (270-824-7532)
Morehead (606-784-6634)
Paducah (270-898-8468)

Web site

<http://www.waste.ky.gov/branches/fo/>

If you need assistance in identifying generator status or related issues, please contact :

Kentucky Division of Waste Management

Frankfort 502-564-6716

Web site

<http://www.waste.ky.gov>

**For multimedia compliance assistance with air quality, water and waste requirements, please contact:
Kentucky Division of Compliance Assistance**

Toll free 800-926-8111

Web site

<http://www.dca.ky.gov>

For additional help in identifying pollution prevention opportunities, contact

Kentucky Pollution Prevention Center

Toll free 800-334-8635

Web site

<http://www.kppc.org>

Disclaimer

This document is to assist you with your concerns about health care facilities, hospitals, doctor's offices, etc., and Resource Conservation and Recovery Act (RCRA). It is intended for **informational purposes only** and **cannot** be substituted for the regulations themselves.

This document was prepared in April 2008 and is based on statutes and regulations in effect at that time. The reader should not rely solely on this fact sheet for regulatory compliance and should instead review the most current statutes and regulations.

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